

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**and**  
**CENTERS FOR DISEASE CONTROL AND PREVENTION**  
  
**convene the**  
  
**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS**

***Atlanta, Georgia***  
***June 4-5, 2003***

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**RECORD OF THE PROCEEDINGS**

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# DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION

## ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS

*June 4-5, 2003  
Atlanta, Georgia*

### **Minutes of the Meeting**

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on June 4-5, 2003 at CDC's Corporate Square Facility, Building 8, in Atlanta, Georgia.

#### ***Opening Session***

Dr. Masae Kawamura, the ACET Chair, called the meeting to order at 8:33 a.m. on June 4, 2003. She welcomed the attendees to the proceedings and particularly recognized the new ACET members and liaisons. She opened the floor for introductions; the following individuals were present to contribute to the discussion.

#### **ACET Members**

Dr. Masae Kawamura, Chair  
Dr. Jeffrey Douglas  
Dr. Michael Fleenor  
Ms. Teresa Garrett  
Dr. David Gonzales  
Ms. Harriet Gray  
Ms. Sara Loaiza  
Ms. Eileen Napolitano  
Dr. Stephen Puentes

#### **Ex Officio/Liaison Members**

Dr. Eric Blank (APHL)  
Ms. Georgia Buggs (OMH)  
Dr. Henry Blumberg (IDSA)

Dr. James Cheek (IHS)  
Dr. Raymond Chinn (HICPAC)  
Ms. Fran Dumelle (ALA)  
Dr. Fred Gordin (ATS)  
Dr. James McAuley (CCCS)  
Dr. Sheldon Morris (FDA)  
Dr. Lee Reichman (ACCP)  
Dr. Randall Reves (NTCA)  
Dr. Gary Roselle (VA)  
Ms. Rachel Stricof (APIC)  
Dr. Diana Schneider (DIHS/ICE)  
Dr. Michael Tapper (SHEA)  
Ms. Theresa Watkins-Bryant (HRSA)

**Designated Federal Official**

Dr. Ronald Valdiserri,  
Executive Secretary

**CDC Representatives**

Dr. Harold Jaffe, NCHSTP Director  
Dr. Kenneth Castro, DTBE Director  
Mr. Greg Andrews  
Ms. Lori Armstrong  
Mr. Subroto Banerji  
Dr. Jose Becerra  
Ms. Gabrielle Berenson  
Ms. Melanie Clair  
Mr. Dave Crowder  
Ms. Laura Daniels  
Mr. Nickolas DeLuca  
Mr. Reginald Edwards (Contractor)  
Ms. Paulette Ford-Knights  
Ms. Judy Gibson  
Dr. Michael Iademarco  
Dr. Paul Jensen  
Dr. Jonathan Kaplan  
Ms. Amera Khan  
Ms. Ann Lanner  
Dr. Kayla Laserson  
Dr. Mark Lobato

Ms. Jessica MacNeil  
Dr. Bereneice Madison  
Dr. Robert Martin  
Ms. Suzanna Marks  
Mr. Scott McCombs  
Dr. Marisa Moore  
Dr. Mary Naughton  
Dr. Thomas Navin  
Dr. Richard O'Brien  
Ms. Kathryn O'Toole  
Mr. Paul Poppe  
Mr. Bob Pratt  
Dr. Zachary Taylor  
Dr. Ed Thompson  
Dr. Andrew Vernon  
Dr. Gregory Wagner  
Dr. Wanda Walton  
Mr. Todd Wilson

**Invited Presenter**

Dr. Stephanie Bailey (Tennessee DOH)

**Participants**

Ms. Carol Pozsik (TB Consultant)  
Mr. John Seggerson (Public)

Dr. Ronald Valdiserri, the ACET Executive Secretary, reminded the members that all comments are a matter of public record since meetings are open to the media and general public. All members are asked to complete and submit financial disclosure forms. Members with a conflict of interest on a particular issue should recuse themselves from voting or participating in the discussion. Dr. Ed Thompson, the CDC Deputy Director for Public Health Services, also welcomed the attendees to the meeting. On behalf of Dr. Julie Gerberding, the CDC Director, he thanked the members for committing a great deal of time, effort and expertise that will be required to serve on ACET and participate in the TB elimination effort.

## ***Role of ACET***

Chair's Perspective. Dr. Kawamura explained that ACET is an external advisory group to the HHS Secretary and CDC Director. In partnership with CDC, ACET has played a critical role in establishing the foundation and future direction of TB control by providing recommendations and publishing guidance in the *Morbidity and Mortality Weekly Report (MMWR)*. ACET's current role is to refine contact investigations and other TB control strategies as well as to accelerate the decline by addressing unresolved issues, including TB control in low-incidence areas, the Southeastern United States, immigrants and other at-risk populations.

In terms of the elimination effort, TB control has been established with CDC's standardized methods for the United States. Although adequate funding to implement these guidelines in high burden areas resulted in a sharp decline of TB rates over the past ten years, current funding is insufficient to eliminate TB. CDC's allocation of ~\$110 million in FY'02 was much lower than the \$528 million estimate to implement the Institute of Medicine's (IOM) recommendations. Planning, policy and guidelines are needed to address high burden groups, while partnerships with organizations outside of TB control are needed for targeted testing and treatment of latent TB infection (LTBI).

To assist in the elimination effort, ACET is charged with bringing TB issues to national attention, particularly those that have a national impact, require development, are unable to be addressed at the local level, or need national support. ACET is also responsible for reviewing and evaluating CDC activities, guidelines and other national policies that impact TB control; providing input and recommendations; and monitoring TB control and elimination efforts. ACET fulfills its charge by forming issue-specific workgroups; publishing results and recommendations; providing direct feedback to CDC during meetings; participating in consultations with outside organizations; collaborating with other TB groups; and communicating with the HHS Secretary.

ACET will continue to play an important role in TB control and elimination by focusing on current TB reservoirs, such as homeless persons born in U.S. inner cities, blacks in rural Southeastern states, legal immigrants, undocumented persons, and TB along the U.S./Mexico Border. The epidemiology of TB should be reviewed on a continual basis to identify cases in Native Americans or other unexpected populations. In the future, ACET will need to play a bigger role in communicating needs throughout CDC and HHS. Several key challenges and obstacles have been identified in ACET meeting its future goals, such as the tremendous funding gap, adverse effects on state and local funding from a sluggish economy, competing federal priorities, increasing global drug resistance, and imported multi-drug resistance (MDR).

Executive Secretary's Perspective. Dr. Valdiserri reported that ACET operates under the Federal Advisory Committee Act (FACA). The charter outlines the composition and purview of ACET; the document will be distributed during the meeting. Pursuant to FACA, ACET and all other federal advisory committees must adhere to "Government in the Sunshine" policies. Discussions must be as open and transparent as possible; meeting announcements must be published in the *Federal Register*, and all deliberations must be open to the public. Specific criteria must be met before any portion of a public meeting can be closed.

Because meetings are held only two to three times per year, ACET workgroups are formed with ACET members and outside experts as needed to focus on priority issues. After fulfilling its charge, the workgroup is terminated. A workgroup has no independent authority and must brief ACET on its activities on an ongoing basis; ACET then acts upon the workgroup's recommendations. The workgroup on TB Elimination in the Southeast is ACET's only active workgroup at the present time.

In terms of CDC's organization, the Division of Tuberculosis Elimination (DTBE) in the National Center for HIV, STD and TB Prevention (NCHSTP) is responsible for the majority of TB elimination activities. However, the CDC National Center for Infectious Diseases (NCID), National Institute for Occupational Safety and Health (NIOSH) and Public Health Practice Program Office (PHPPO) conduct TB activities as well.

DTBE and the Global AIDS Programs (GAP) focus on international TB control initiatives, but ACET's purview is primarily domestic. As an advisory committee, ACET makes recommendations to HHS and CDC. The collaborative relationship between ACET and CDC has been outstanding. Most notably, ACET has made several important policy recommendations and guidelines that have been published. HHS recently recognized ACET's high productivity in a survey of all federal advisory committees.

CDC provided additional comments to respond to the new members' questions about ACET's role and function. Because members are special government employees while serving on ACET, members should inform CDC if the media requests a statement about ACET's publications or other activities. CDC will then advise on the appropriate spokesperson to respond to the press. However, members are free to communicate with the media as an individual in the public or an expert in local activities and other non-ACET initiatives.

ACET does not provide CDC with guidance about funding of specific programs or individual projects due to established procurement and competition rules. Since some members are also CDC grantees, a conflict of interest would arise if ACET was allowed

to influence funding decisions and the selection of grantees or contractors. However, CDC may ask ACET members to serve on external peer review panels as individual experts. CDC welcomes guidance from ACET about progress toward TB elimination and TB research, programs or activities that should be prioritized.

ACET cannot collectively lobby for TB funding, but members can serve as advocates to advance the TB elimination effort. Members who represent themselves or their specific organizations can make public comments on funding needs or any other aspect of the TB elimination effort. ACET members are selected by the Office of the HHS Secretary, have voting rights, must complete financial disclosure forms, and are subject to FACA rules and regulations. Liaisons are non-voting members who represent organizations with an interest in lung health and TB. *Ex officios* have no voting rights and generally represent federal agencies.

### **Overview of CDC TB Elimination Activities**

DTBE. Dr. Kenneth Castro, the DTBE Director, explained that DTBE functions as the national TB program in the United States. DTBE is responsible for active TB surveillance, outbreak response, epidemiologic studies, program support, clinical and operational research, training and education activities, and global TB initiatives. The 68 areas funded by DTBE include all 50 states, territories and several large cities. DTBE's internal partners include GAP, NCID, NIOSH, PHPPO and the Division of Global Migration and Quarantine (DGMQ). External collaborators include the Health Resources Services Administration (HRSA), Food and Drug Administration (FDA), Indian Health Service and National Institutes of Health (NIH).

Morbidity from TB cases steadily declined in the United States for more than 30 years, but an unprecedented increase was seen from 1985-1992. To address the resurgence of TB, a national action plan to combat MDR-TB was published in 1992 in the *MMWR* with several guidelines: recommend initial treatment with standardized four-drug regimens for all persons with active TB; rely on directly observed therapy (DOT) to assist in course completion; implement laboratory methods to obtain real-time drug resistance testing; monitor drug resistance trends since 1993; implement infection control precautions; and develop new diagnostic tests, drugs and vaccines.

After reported cases in the United States decreased 43.5% from 1982-2002, CDC contracted IOM to conduct a study on the feasibility of eliminating TB. The IOM Committee first reviewed and evaluated several areas in TB and then outlined five general conclusions in its published report entitled *Ending Neglect*. Control should be

maintained while adapting to declining incidence. Decline should be accelerated through increased treatment of persons with latent infection. Diagnostic tests for LTBI, new drugs, vaccine and other tools needed for ultimate elimination should be developed. U.S. engagement in global efforts should be increased. Support should be mobilized and progress should be measured. CDC's report to respond to *Ending Neglect* has been published. The Federal TB Task Force report to respond to *Ending Neglect*, a complementary report to CDC's document, is currently undergoing the clearance process.

In terms of interventions for TB prevention and control, adequate infection control procedures must be implemented to prevent transmission of airborne particles from an individual with active respiratory TB to a susceptible contact. Persons with active TB must be identified and placed in rooms with sufficient ventilation. Engineering controls must be applied and personal respiratory protection must be used. TB cases should complete a full course of treatment and BCG immunization should be given. Targeted testing and treatment must be administered to prevent LTBI cases from becoming secondary cases of active TB.

This framework was published in 1994 in the *MMWR* as "Guidelines for Preventing the Transmission of *Mycobacterium Tuberculosis* in Health Care Facilities." The guidance is being revised and should be distributed to ACET by the end of June 2003. CDC expects to announce the public comment period of the document in the *Federal Register* by mid-July 2003. Several tools are currently available for TB diagnosis and treatment, but other diagnostic tests are still needed, such as DNA fingerprinting, same-day drug susceptibility testing and other rapid methods; effective short-course chemotherapy; TB drugs that can be completed  $\leq 2$  months or taken once per week; and improved evaluations of patient outcomes.

BCG is not recommended for routine use in the United States due to its low efficacy rate of 50% and interference in interpreting tuberculin skin test results. However, BCG is recommended for children who cannot tolerate drugs for LTBI; children who live with an adult with MDR-TB; and health care workers if MDR-TB transmission is apparent despite infection control measures. Overall, a vaccine that is better, safer and more effective than BCG is needed, particularly for individuals with HIV co-infection. Additionally, persons on BCG may ignore the need to follow through with infection control precautions.

Several tools and regimens are currently available for LTBI diagnosis and treatment, but effective and reliable tests are still needed to treat persons with immune suppression and identify individuals at risk of progressing from latent to active TB. LTBI drugs that can be completed  $\leq 2$  months or taken once per week are needed as well. Challenges identified in the TB elimination effort in the United States can be addressed through

several mechanisms. Sustained support for programs, evaluation, capacity and proficiency should be secured to avoid complacency with low TB rates and respond to outbreaks, TB health disparities and TB in foreign-born groups. Contributions to global TB control should be enhanced. Genotyping, the TB Vaccine Blueprint and other new tools should be identified and implemented.

PHPPO. Dr. Robert Martin described approaches taken by the Division of Laboratory Systems (DLS) to improve TB laboratory capacity. In partnership with other federal agencies and laboratory organizations, DLS addresses the quality of laboratory testing in domestic and international public health and clinical laboratories through laboratory systems development, standards development, research and training. Approximately 70% of medical decisions are based on 7-10 billion laboratory tests performed each year in the United States. The Model Performance Evaluation Program (MPEP) was developed in 1985 as a voluntary external quality assurance mechanism for HIV testing and now includes *M. tuberculosis* nucleic acid amplification and drug susceptibility testing.

MPEP assists laboratories in evaluating and maximizing testing skills; allows CDC to monitor laboratory practices; assesses and develops training needs; evaluates inter-laboratory reproducibility of test results; and provides educational opportunities. Unlike traditional proficiency testing programs, MPEP is voluntary and does not charge a participation fee. Both intra- and inter-laboratory comparisons are available and only aggregate data are reported. Laboratories do not receive individualized reports with scores. Some MPEP components are available to laboratories outside the continental United States.

Currently in the United States, 1,938 laboratories are enrolled in Clinical Laboratory Improvement Amendment (CLIA) proficiency testing. When DLS sent shipments of specimens for laboratory testing in January 2003, a survey was included for nucleic acid testing and drug susceptibility testing of *M. tuberculosis* and non-tuberculous mycobacteria. Laboratories were asked to provide details in several areas, such as test methods used, biosafety levels of the facility, test volume, quality control practices, drugs, interpretation and inter-laboratory agreement of results. Survey participants included hospitals, health departments, independent facilities and other types of laboratories. The survey showed the following results.

Laboratories tend to use recommended rapid methods when providing test services, but many facilities are not applying fluorescence microscopy, rapid or broth culture, rapid identification methods, or rapid or broth drug susceptibility testing. Specimens generally arrive at hospital laboratories in less than 12 hours, but the time increases to 25-48 hours for state laboratories. As a result, state laboratories cannot meet the standard of reporting a smear within 24 hours. TB control is negatively impacted by delays of AFB-

positive reporting because providers are unwilling to initiate treatment without a laboratory report. Despite new technologies, mycobacteriology still requires referrals and different levels of service. Coordination between laboratories in public and private sectors needs to be improved for referral services. Proscriptive solutions have been ignored.

Technology changes and many combinations of methods and referrals are beyond a single recommendation. An operational research program to develop and support models of referral has not been developed. The survey results can be accessed on the CDC web site. The bioterrorism model proposes to design a process to improve collaboration and communication among clinical laboratories, laboratories in the Laboratory Response Network, and other public health facilities. This model should be reviewed and applied in the TB arena.

DLS has been involved in developing the National Laboratory System (NLS) to ensure consistency among laboratories in all settings. In 2001, DLS provided funding to Michigan, Minnesota, Nebraska and Washington to create and implement state-based demonstration projects of NLS. The four models were completed in 2002; data show that the projects were successful. DLS was provided funds to conduct a formative evaluation of the NLS demonstration projects. The ultimate goal of this activity will be to expand the NLS models to ensure that laboratories in all 50 states have strong relationships with clinical laboratories.

Other models of public/private cooperation for mycobacteriology include the Fast Trak Service in Florida and New York; inoculation and referral of liquid cultures in California, New Mexico and Utah; and promotion of rapid methods and coordinated services between public health and private laboratories in Minnesota, Washington and Wisconsin. DLS is convening regional meetings for states to share lessons learned about laboratory testing at the regional level. The meetings are also being held to develop mechanisms within states and regions that can resolve problems laboratories encounter in adhering to national guidelines.

NIOSH. Dr. Gregory Wagner reported that NIOSH is responsible for several occupational safety and health activities: laboratory and field research; technical assistance to employers, workers, states and other government agencies; training to professionals; support to Epi-Aids, international assistance projects and other CDC investigations; and workforce screening and surveillance. One of NIOSH's TB-related laboratory investigations focused on the effectiveness of ultraviolet germicidal irradiation. The study found that during constant generation experiments, culturable airborne bacteria were reduced 46%-97%. Inactivation rates decreased 20%-40% when relative humidity was above 75% in the room. Uneven irradiation distribution in the room decreased inactivation by standard ventilation rates.

NIOSH and DTBE are currently collaborating on new approaches for medical screening of latent TB cell-mediated immunity. Hypotheses are being tested to demonstrate that mediated immunity to *M. tuberculosis* can be measured as a biomarker of LTBI. Research is also underway focusing on proteomic approaches that can be used to develop systems for rapid diagnosis of TB infection. The study aims to prove that an analysis of proteomic patterns of expression by *M. tuberculosis* and the host in response to *M. tuberculosis* infection can assist in rapid diagnosis.

NIOSH is also responsible for certifying respirators, conducting research on performance, developing improved fit methods, and evaluating respirator function. A NIOSH study with a limited number of respirators and participants with different facial characteristics showed the following results. The variability in performance is substantial even among respirators that meet minimum certification standards. Fit testing enhances performance, but the best performing respirators have less value from fit testing than worst performing respirators. Respirators with inherently good fitting characteristics will perform better than poor respirators after fit testing. Well-designed respirators that are fit tested provide the most protection. Respirators performed comparably with filtration capability, but the leakage around the face seal was problematic. The study findings were recently published and will be distributed to ACET before the meeting is adjourned.

NIOSH is still interested in encouraging the development of respirators with inherently good fit characteristics and having manufacturers communicate fit characteristics of their respirators to potential users. There are currently no regulations requiring this and any regulatory process would be quite slow. NIOSH is considering non-regulatory approaches that might achieve this objective.

NIOSH has developed several mechanisms to communicate information and provide technical assistance concerning proper use of respirator protection. A videotape on TB respiratory protection in health care settings was widely distributed for training programs to demonstrate proper respirator use and care. NIOSH recently released a companion DVD for administrators of respiratory protection programs in health care settings. NIOSH realizes that risks to workers using respirators are different based on the specific hazard and work setting, but general approaches to assure adequate respiratory protection are quite similar across different work settings.

Several ACET members pointed out that the Health Care Infection Control Practices Advisory Committee (HICPAC) is in the process of finalizing its isolation guidelines, which include issues related to respiratory protection for diseases other than TB, such as SARS. Because recommendations from CDC and HICPAC should be as consistent as possible, ACET and HICPAC should be provided more time than two weeks to review CDC's guidelines before the document is submitted to the *Federal Register*.

CDC's document should also be shared with the American Thoracic Society (ATS)/ CDC/Infectious Disease Society of America (IDSA) workgroup that is currently revising the TB control statement.

ACET extensively discussed the recent announcement by the Occupational Safety and Health Administration to retract its proposed rule to protect workers from TB in hospitals, prisons and other high-risk facilities. ACET's deliberations on TB elimination activities by DTBE, NIOSH and PHPPO resulted in several suggestions for future agenda items: new LTBI diagnostic tools, TB vaccine development and the updated TB infection control guidelines. Consideration should also be given to ACET evaluating the success or failure of Quanti-FERON by monitoring the effectiveness, efficacy and availability of the test. Representatives from STOP TB, the Global Alliance for TB Drug Development and the TB vaccine development effort should be invited to present at the meeting.

CDC confirmed its commitment to distribute the TB infection control guidelines to ACET and HICPAC before submitting the draft to the *Federal Register* for public comment. Because internal revisions and the CDC cross-clearance process are requiring more time than initially expected, CDC will share the draft with ACET members, liaisons and HICPAC no later than July 1, 2003. However, every effort will be made to circulate the document sooner than this date. ACET and HICPAC will not be allowed to distribute the document further since the draft will not be cross-cleared.

After the two-week review period, CDC will provide additional time to consider comments by ACET and HICPAC and revise the draft accordingly prior to publication in the *Federal Register*. CDC prefers that individual members and liaisons submit comments rather than developing a collective ACET response. ACET and HICPAC will have another opportunity to provide input while the public comment period is open in the *Federal Register*. With respect to other TB elimination activities, the Bill and Melinda Gates Foundation contributed \$25 million to a pharmaceutical company to advance TB vaccine development. The TB Vaccine Blueprint estimates that 20 years and ~\$800 million will be required to develop a safe and effective TB vaccine. CDC agreed that potential candidates for new vaccines, field trials of drugs and research needs should be placed on a future ACET agenda.

### ***NCHSTP Director's Report***

Dr. Harold Jaffe's update covered the following areas. First, Dr. David Fleming, the CDC Deputy Director for Science and Public Health, will take a position with the Bill and

Melinda Gates Foundation in mid-June 2003. Dr. Dixie Snider, the CDC Associate Director for Science, will fill Dr. Fleming's position until a permanent replacement is appointed. Dr. Andrew Vernon was recently appointed as the NCHSTP Associate Director for Science. Dr. John Douglas will begin serving as the Director of the NCHSTP Division of STD Prevention in July 2003. Recruitment efforts are underway for a new Associate Director for Health Disparities in the NCHSTP Office of the Director. The agreement to transfer HIV, STD and TB Laboratories from NCID to NCHSTP is expected to be signed by July 1, 2003. Dr. Jonathan Kaplan will serve as the Director of the NCHSTP Division of AIDS, STD and TB Laboratory Research.

Second, the General Accounting Office is reviewing government science advisory committees. The report is due in January 2004; ACET was not selected for the review. Third, ~\$1.2 billion was allocated to NCHSTP in FY'03. Of \$60 million in program increases, \$4 million was appropriated for TB elimination. Of the final appropriation of \$700 million, \$135.6 was allocated to DTBE. The President's FY'04 budget request of \$131.3 million for TB is \$1.3 million less than the FY'03 request. Fourth, the President signed the United States Leadership Act Against HIV, Malaria and TB into law on May 27, 2003. The bill authorizes the creation of a coordinator position with the U.S. State Department and an expenditure of \$15 billion over the next five years in 12 countries in Africa and two in the Caribbean. The actual amount to be allocated to CDC from the bill has not yet been determined.

The Comprehensive Tuberculosis Elimination Act of 2003 was introduced on May 13, 2003. The legislation amends sections of the Public Health Service Act that address the role and scope of ACET. The recommendations call for ACET to be more involved in global and cross-border TB control issues; more representatives of federal agencies to serve as ACET members; and an FY'04 appropriation of \$528 million for CDC's TB control efforts. The STOP TB Now Act was introduced highlighting the STOP TB partnership. An additional authorization of \$30 million to CDC was proposed to implement global TB activities. Both bills have been referred to the House.

### ***DTBE Director's Report***

Dr. Castro's update of recent DTBE activities was framed in the context of six goals CDC established to respond to *Ending Neglect*. To maintain control, FY'03 cooperative agreements totaling \$116.3 million were awarded to 68 areas for laboratory support and special projects. Forty public health advisors and eight physicians were assigned to the field to collaborate with local programs; four field positions are currently vacant. A

workgroup was formed to place a stronger emphasis on program evaluation. An Epi-Aid was used to respond to nine requests for TB epidemiologic assistance in 2002.

These settings included a TB cluster in a low-incidence county in Oklahoma; cases in cancer patient hostels in Illinois and Missouri; a nosocomial HIV-related outbreak in Washington, DC; an Indian reservation in North Dakota; and a case of MDR-TB in Georgia. DTBE's focus on policies, training and education is continuing. Consultation and training were provided to Model Centers; a program manager's training session was convened in October 2002; the number of web-based publications was increased; and Quanti-FERON testing guidelines were presented to ACET. The ATS/CDC/IDSA treatment guidelines were published in a journal in February 2003 and will be updated and reprinted in the *MMWR*. Clearance, revision, evaluation and publication of the TB infection control guidelines are underway.

To accelerate the decline, new projects were initiated based on ACET's recommendations. These activities focus on low-incidence areas; high TB rates in Southeastern states and among U.S.-born blacks; TB along the U.S./Mexico Border; improvement of electronic notification and monitoring of immigrants and refugees; aggregate reports of program evaluations; and genotyping of *M. tuberculosis* isolates. Of nine applicants responding to the genotyping program announcement, two were recommended for further consideration.

To develop new tools, data collected over five years from the Genotyping Surveillance Network were published in November 2002. A GENE Team was established to develop universal DNA fingerprinting guidelines and conduct research to enhance TB control. Two studies under the TB Trials Consortium (TBTC) are examining the role of moxifloxacin and the efficacy of once-weekly isoniazid (INH) and rifapentine (RPT) compared to nine months of INH for LTBI. Evaluations of new LTBI diagnostic tests are ongoing. Epidemiologic research by the TB Epidemiology Studies Consortium (TBESC) is focusing on TB in pediatric populations, foreign-born groups and contacts.

To increase global involvement, technical support is being provided to 16 countries: a strategic approach in Mexico, the Philippines and Vietnam; an expansion of DOTS in Brazil, India and Russia; a focus on MDR-TB in the Baltic States, Peru and Russia; and emphasis on TB/HIV co-infection in Botswana and countries with a GAP mission. A proposal has been made to reorganize international activities into a branch with 14 staff in six countries. The Coordinating Board and workgroups are still engaged in the STOP TB partnership. The collaboration with the U.S. Agency for International Development (USAID) and TB Coalition for Technical Assistance is ongoing to leverage international resources to provide technical support for TB activities.

To mobilize support, joint efforts with ATS, IDSA, the American Lung Association (ALA) and other external partners are continuing. DTBE presented briefings at the request of Congressional members and participated in World TB Day in March 2003. Guidelines and scientific publications were communicated to media and media guidelines for outbreaks are currently being developed.

To track progress, annual TB morbidity and mortality rates for 2002 were published in the *MMWR* in March 2003. The data showed a total 15,078 cases reported in 2002 with a rate of 5.2/100,000 persons. Completion of therapy for all TB cases is continuing to be monitored. Consistent TB indicators are being developed for *Healthy People 2010* and the Government Performance and Results Act. Program evaluation was the focus of a workshop in 2002 by the National TB Controller's Association (NTCA); a post-graduate course sponsored by DTBE; and a new unit in the Field Services Branch. An initiative was officially launched in March 2003 to monitor outcomes with the U.S./Mexico binational card.

ACET encouraged CDC to improve current methods to train and educate front-line medical providers. Diagnosis and treatment can be delayed by six months or more during an outbreak. Traditional consultation and medical expertise from Model Centers should be expanded as well. ACET was pleased that DTBE is developing guidelines to communicate TB activities to the media. CDC agreed that stronger efforts must be made to partner with physician organizations for pediatricians, internists, family practitioners and other primary care providers. Physician knowledge must be enhanced about screening, identifying high-risk persons and ordering diagnostic tests. In addition to expert consultation from Model Centers, CDC welcomed other recommendations from ACET on this issue.

### ***Report on TB Legislation***

Ms. Fran DuMelle serves as the ACET liaison to ALA. She outlined the Comprehensive Tuberculosis Elimination Act (CTEA) of 2003. A workgroup was formed to review the IOM recommendations, examine the TB Public Health Code, and list activities that may fall under a legislative purview. The workgroup identified four recommendations in *Ending Neglect* that should be addressed in legislation. Categorical funding at the federal level should be maintained. Resources should be provided to maintain excellence in TB services. Resources for research should be increased for new diagnostic tools, LTBI treatment and vaccine development. U.S. involvement in global TB control should be increased.

The major sections of CTEA propose that existing responsibilities for several groups be amended in the Public Health Code. For ACET, the HHS Secretary should be provided with advice to make progress toward TB elimination. A national plan should be developed that considers the IOM recommendations, addresses the development and application of new technologies, and reviews progress toward TB elimination. Recommendations should be developed to guide U.S. involvement in global and cross-border TB control activities with a focus on countries where a high incidence of TB directly affects the United States.

For DTBE, the division should be renamed to the “National Program for Tuberculosis Elimination” in the Public Health Code. Research conducted through TBESC and TBTC should be prioritized. Regional capabilities should be developed for prevention, control and elimination of TB, particularly among populations disproportionately affected by TB and in low-incidence regions. The implementation of public information and education programs as well as support to Model Centers should be continued. Collaborative efforts should be expanded with international organizations through the Committee on Interagency Collaboration for TB Elimination. Activities should be evaluated with annual reports from ACET. The assessment should include ACET’s opinion on the extent to which IOM recommendations were implemented.

For NIH, TB Academic Awards and TB/Pulmonary Infection Awards should be presented to faculty at academic institutions for outstanding efforts in the TB field. Funding should be provided for TB vaccine development based on recommendations from the Blueprint for TB Vaccine Development. Support should be given to the International Training Program. CTEA proposes \$528 million for the CDC National Program and \$250 million for NIH. A strong lobbying campaign by several organizations will soon be launched to advance CTEA appropriations and authorization. Advocates for the bill are extremely pleased that Congressional interest in TB has significantly increased over the last two years.

ACET suggested that TB lobbyists and advocates replicate the HIV model in which aggressive actions were taken throughout the country and much more funding was allocated. Efforts must be made at the local level to advance TB legislation. CTEA should also emphasize the need for additional funding and resources at the state level.

### ***Update on TBTC***

Dr. Richard O’Brien, Chief of the DTBE Research and Evaluation Branch, explained that TBTC is funded by CDC as an investigator-driven collaboration in TB clinical research.

The mission of TBTC is to conduct programmatically relevant clinical research on the diagnosis, treatment and prevention of active TB and LTBI. Despite the availability of effective TB treatment, new drugs and drug regimens are needed to shorten or simplify treatment of persons with active TB; provide more effective treatment of patients with LTBI; and improve treatment of MDR-TB. CDC is mandated by the U.S. Public Health Service to conduct TB therapy trials.

The global infrastructure to conduct TB trials weakened in the early 1980s as interest in TB decreased. However, the capacity to conduct high-quality TB trials was reestablished in 1995 when CDC initiated TBTC Study 22, the rifapentine (RPT) trial. TBTC currently includes 26 clinical sites in the United States, Canada and Brazil, but three additional international sites are expected to be funded in Africa with FY'03 dollars. The geographic location of several sites address the high burden of TB in Southeastern states, including Arkansas, Georgia, North Carolina, Tennessee and Texas. The initiative has solid links to local TB control programs and is operated under formal bylaws and policies. TBTC activities are communicated through e-mail messages, conference calls, semi-annual meetings, CDC's Data and Coordinating Center, and an external Data and Safety Monitoring Board.

A contract research organization provides onsite monitoring of trials, ensures compliance with regulatory requirements and serves as a quality control component of ongoing trials. TBTC also closely collaborates with TB drug manufacturers, biological companies and pharmaceutical companies. TBTC is organized with a Steering Committee, an Executive Affairs Group, four committees, two workgroups and protocol teams. TBTC studies have focused on RPT, rifabutin in TB/HIV co-infected persons, INH resistance and intolerance, and moxifloxacin. Laboratory and pharmacokinetic studies linked to active treatment protocols have been performed as well. Details about TBTC's major research efforts are outlined below.

In Study 22, adult patients with drug-susceptible pulmonary TB were enrolled after completing a standard two-month initial regimen and then randomized to recommended CDC regimens for INH-RPT or INH-rifamycin (RIF). After the four-month therapy in the study phase, patients were followed for two years for relapse or recurrent TB. From April 1995 to November 1998, 1,004 HIV-negative and 71 HIV-positive patients were enrolled. The HIV-positive arm was closed after four relapses occurred with acquired rifampin (RIF) resistance. Randomization was balanced except for significantly more patients with cavitory disease and a positive sputum culture at two months in the RPT arm. These two variables along with underweight and white race were the factors associated with failure and relapse. Relapse rates were >20%.

Study 22 concluded that a once weekly RPT-INH regimen provided an effective continuation phase treatment in HIV-negative patients with non-cavitory pulmonary TB.

Patients with cavitary TB with positive sputum cultures after two months of therapy should have treatment extended. Increased doses of RPT or a better companion drug than INH may provide for more effective once-weekly treatment even for patients at higher risk and those with HIV. Study 22 results greatly influenced the new treatment guidelines that were recently released by the ATS/CDC/IDSA workgroup. In Study 25, 150 patients were enrolled in three treatment arms to determine whether higher doses of RPT-INH would improve the efficacy of once-weekly regimens. The study endpoints included adverse events and drug discontinuation.

Treatment was extended for 12 weeks for 17 Study 25 patients with cavitary TB and a positive sputum culture after two months. The relapse rate from the 600 mg once-weekly dose of RPT for 12 months was 6% in Study 25, while the relapse rate from the same regimen for six months was 22% in Study 22. The 900 mg once-weekly dose of RPT was found to be the most safe and effective. In Study 26, highly intermittent therapy for LTBI is being evaluated by comparing the efficacy and tolerability of 12 doses of once-weekly INH/RPT to nine months of daily INH. Eligibility criteria for enrollment in the study include males and non-pregnant females  $\geq 12$  years of age with evidence of LTBI; an increased risk of TB from HIV infection, TB skin test conversion or contacts with infectious TB patients; or evidence of previous TB based on chest radiograph.

Approximately 4,000 patients per arm will be needed for Study 26 to demonstrate equivalence between the two regimens. Of 25 TBTC study sites, 1,757 patients were enrolled in Study 26 as of June 3, 2003. Quality assurance for Study 26 is being measured in terms of eligibility criteria, correct number of doses, doses administered within prescribed times and at correct intervals, and rates of visits, completion and retention. TBTC's future plans for RPT are to increase capacity for enrollment in Study 26 and implement a pediatric PK study. Implementation of treatment studies of active TB using a better companion drug than INH is being considered, but continued support from the manufacturer of RPT is questionable.

Fluoroquinolones (FQs) are another area of interest in TBTC because the drugs are now commonly used for the treatment of MDR-TB despite the absence of randomized controlled trials. New clinical and experimental data suggest that FQs may shorten the total duration of therapy for TB patients and improve the efficacy of once-weekly RPT-based treatment. Of all FQs, TBTC is most interested in moxifloxacin due to the drug's long half-life and ability to be active against TB. Experimental studies in mice showed that moxifloxacin is as bactericidal as INH in the initial phase of TB treatment. A daily regimen of moxifloxacin, rifampin and pyrazinamide for three months was found to have comparable activity to six months of standard treatment. Moxifloxacin added to RPT may permit once-weekly treatment after two weeks of daily therapy.

In Study 27 of moxifloxacin, AFB-positive adult patients with suspected TB will be enrolled and randomized into one of four arms. The sample size will include 75 patients per arm; both HIV-positive and -negative persons will be enrolled. The study endpoints will include sputum culture conversion after two months, safety and tolerability. The protocol for Study 27 has been approved by the CDC Institutional Review Board (IRB) and several local IRBs. Approval of local consent forms from the CDC IRB is pending. A cooperative research agreement has been signed with the pharmaceutical company and an investigational new drug permit was obtained from FDA. Moxifloxacin, ethambutol and the placebo are ready to be shipped from the CDC drug service.

In response to the IOM recommendation to maintain and expand TBTC, funding was increased to add three new international sites, support 12 full-time positions, conduct Study 27, implement the pediatric PK study, and refine the Data and Coordinating Center to improve the timeliness of reporting and analysis. With respect to another regimen, CDC previously recommended two months of rifampin and pyrazinamide for LTBI. After severe liver injuries and deaths were reported, CDC, ATS, FDA and IDSA are now inclined to recommend against the use of this regimen for the treatment of TB infection in HIV-positive and -negative patients. After the groups reach consensus, a "Notice to Readers" will be published in the *MMWR* and adverse events from the regimen will be analyzed in more detail in a peer-reviewed journal.

TBTC has been instrumental in identifying high-risk TB patients; defining a better regimen for LTBI; modifying treatment recommendations; improving clinical trials and IRB practices; defining the value of serum drug levels; fostering new clinical trials networks; and bridging TB control and research by strengthening links between programs and academic centers. In a short period of time, TBTC has become an internationally recognized group conducting high-quality TB clinical research. Results from TBTC studies have influenced treatment guidelines. TBTC has been successful in enrolling racial/ethnic groups and women in trials. The expansion of TBTC in international sites with a high incidence of TB will significantly enhance capacity to enroll patients in active treatment trials. However, increasing enrollment in LTBI studies continues to be a challenge of TBTC.

### ***Update on the CDC/Bureau of Immigration and Customs Enforcement (ICE) Collaboration***

Dr. Mark Lobato of DTBE reported that the CDC/ICE workgroup was established in response to problems identified by local TB programs in preventing and controlling TB along the U.S./Mexico Border. Local programs found that interruptions in TB treatment

are common among patients in ICE custody. Partially treated deportees who return to the United States often result in drug-resistant TB. Communication is inadequate among TB programs, holding facilities and federal agencies. CDC acknowledged these issues in an *MMWR* article in January 2001.

TB control and prevention along the border was revisited when ACET's recommendation for HHS and the Department of Justice to form an interagency policy development group was published in the *MMWR* in May 2003. The CDC/ICE workgroup that was established has convened four meetings to date. The problem was further defined when the workgroup conducted a chart review of 100 TB cases in FY'01-FY'02 reported by Immigration and Naturalization Services (now ICE) service processing centers or contract facilities. A mechanism for case reporting was also devised. NTCA as well as state and local TB programs along the border have now been incorporated into the workgroup process. The Mexican TB Program and other border stakeholders will be represented at the upcoming workgroup meeting in July 2003. Plans will be made to transfer care from ICE custody to Mexican health authorities; the Arizona "Meet and Greet" Project will be used as a model in this effort.

Dr. Diana Schneider of ICE explained that the Department of Homeland Security (DHS) began operations on March 3, 2003 and Detention and Removal functions formerly under the Immigration and Naturalization Services (INS) were transferred to DHS. The Division of Immigration Health Services (DIHS) is under the HHS umbrella through HRSA. ICE and the Division of Immigration Health Services (DIHS) are among the components organized under DHS. DIHS provides direct health services through eight service processing centers and three contract detention facilities as well as managed care services through contract detention facilities and jails throughout the country. DIHS has also established an emergency medical response team to support mass influx operations. Of 20,000 persons in detention each day, 5,000 are in facilities staffed by DIHS and 15,000 are in jails.

In terms of TB, cases are identified at the detention facility by the DIHS medical clinic. The initial medical screening for physical and mental health conditions includes a chest x-ray for TB at facilities equipped with teleradiology services and conventional screening at lower risk facilities. From the service processing centers with tele-radiology capacity, DIHS can obtain chest x-ray results in less than four hours. TB cases in ICE custody are housed in a contract detention facility or ICE contract jail and reported to the health department by the jail, community provider or laboratory. DIHS is undertaking several efforts to improve capacity in identifying cases. Systems are being established for health departments and jails to notify DIHS of TB cases; a DIHS managed care coordinator will then provide case follow-up. A TB surveillance program was initiated in April 2003 and a partnership was established with NTCA to encourage communication between DIHS and state and local health departments.

A process is being designed for health departments that are following TB cases in the community. If an individual is apprehended by ICE, the health department or jail will notify DIHS and the managed care coordinator will establish eligibility. Individuals apprehended by ICE may or may not be placed in custody. Persons in ICE custody are held in a detention facility with the onsite DIHS medical clinic, a contract facility without the DIHS medical clinic or a local jail under an agreement with ICE/DIHS managed care. After the apprehension, the detainee is detained or released until a hearing is held at a later time may voluntarily return to the country of origin. DIHS has no involvement with persons who are not in ICE custody.

After TB cases are identified and known to be in custody, DIHS coordinates and communicates with government agencies and non-governmental organizations (NGOs) to provide care in the post-detention period. Although the average length of detention is 22 days, many detainees are only in custody for two days. As a result, the exchange of case information to provide continuity of TB care must be completed in a timely manner. DIHS is developing a program to provide a physical transfer to a public health authority in the country of origin when detainees are removed. Due to conflicting priorities between immigration laws and public health policies, DIHS is challenged by ACET's recommendation to allow TB cases to complete treatment in the United States in the least restrictive environment.

To assist in refining DIHS's communication and coordination process, key representatives from Mexico will be invited to the CDC/DIHS/ICE meeting in July 2002 since the majority of TB cases are from this country. Mechanisms are being developed to implement the transfer-of-care model and emphasis will be placed on methods to address the deportation of MDR-TB cases and other complex cases. DIHS will make efforts to resolve issues related to TB cases conditionally released in the United States, but this option may not be available to persons previously convicted of a felony. ICE attorneys have confirmed that completion of therapy can be listed as a condition of release, but a mechanism to comply with immigration law enforcement must first be established.

A review of 100 charts of detainees in DIHS facilities showed 93 TB cases in FY'01 and FY'02. DIHS's TB case rates upon initial screening were 67/100,000 in FY'01 and 95/100,000 in FY'02 and exceeded national rates. In the two-year period, 60% of active TB cases were deported; 44% were from Mexico; and 50% were from Honduras. Of Mexicans in ICE custody with TB, 85% were deported. Of all detainees with TB who were deported, 62% were from Mexico and 21% were from Honduras.

In the future, efforts will be made to more widely replicate the Arizona "Meet and Greet" Project. In this initiative, the state health department collaborates with the DIHS

detention facility in Arizona in placing a medical hold on TB cases. Physicians on both sides of the border then meet at a specified time to release the detainee to the physician in Mexico. The detainee is then housed in a room for a few days until arrangements can be made in Mexico. DIHS hopes to expand its surveillance activities in the future to determine whether TB cases complete therapy in Mexico. Overall, DIHS acknowledges that TB education must be strengthened at all levels of the immigration process, including immigration judges, sheriffs and jail officials.

ACET suggested that DIHS clearly delineate its transfer-of-care model to the National Association of City and County Health Officials. The organization can then further distribute the information to its 3,000 members to strengthen linkages between DIHS and local health departments.

### ***U.S./Mexico Binational TB Referral and Case Management Project***

Dr. Kayla Laserson of DTBE reported that foreign-born persons represented 50% of the total TB burden in the United States in 2002. Mexico contributed to 25% of this rate; 70% of these TB cases were reported from Arizona, California, New Mexico and Texas. The 2,000-mile border includes four U.S. states, six Mexican states, 27 million inhabitants and >264 million northbound legal crossings per year that complicate TB case management. TB incidence along the border is higher than national rates in both Mexico and the United States. Data collected by CDC in 2001 show that case rates in the United States were 4.5/100,000 at the national level versus 6.9/100,000 along the border. The case rate reported in Mexico in 2001 was 16.2/100,000 at the national level compared to 28.1/100,000 along the border.

CDC surveillance data found that Mexican-born TB patients are approximately twice as likely to move or become lost to follow-up than U.S.-born TB patients. However, the border does not represent a higher incidence of drug resistance than other parts of the country. These issues led border officials to request the development of a comprehensive case management referral system to manage TB patients. In response to this request, the Mexican Secretary of Health (MSH) and HHS Secretary signed an agreement in September 2000 to deepen and broaden bilateral collaboration in addressing migrant health needs, exchanging information, and improving access to health services for migrants and their families.

In November 2000, the MSH and CDC collaborated to develop and implement a binational TB card to ensure continuity of care and completion of treatment for TB

patients who migrate between Mexico and the United States. The binational card was signed by the U.S./Mexico Border Health Commission. The goals of the project are to ensure continuity of care; improve completion of treatment; reduce TB in both countries by responding to needs in the region; prevent drug resistance; coordinate referral of patients between the health systems in both countries; serve as a model for other countries and diseases, particularly HIV; and apply lessons learned from existing referral/counter-referral programs.

These initiatives include CDC binational TB projects, the San Diego County Health Department CureTB, and the Migrant Clinicians Network TBNNet. Pilot sites for the binational TB card project cover California, Mexico, New Mexico, Texas and an ICE detention center in Texas. CDC recently released a program announcement to add new sites to the project. The binational TB card contains a unique identification number to track patients, location where the card was issued, treatment initiation date, date of last dose of TB treatment, treatment regimen, DOT or non-DOT administration of treatment, and toll-free telephone numbers in Mexico and the United States.

The card links to secure databases in Mexico and the United States for providers to access clinical information by telephone and manage the patient's care. To address confidentiality issues, DTBE researched laws in Mexico and the United States and determined that information from the binational TB card can be exchanged so long as the data are used for the case management of a public health issue and not for surveillance or research purposes. On March 12-13, 2003, two training sessions were held in the United States and three were convened in Mexico. The binational TB card project was then launched on March 27, 2003. Additional training sessions will be held in Mexico in June 2003.

Educational materials were developed for specific groups. A project manual containing the protocol, procedural flowcharts and sample forms were designed for project coordinators. Poster size flowcharts, a checklist and maps were created for health care workers. Educational brochures and posters were developed for patients. To date, a "Dear Colleague" letter was distributed to >1,000 partners in the United States, including ACET and migrant clinics. A similar letter and other health promotion activities are being prepared for Mexico. Activities about the project were announced during World TB Day in March 2003. Approximately 50 binational TB cards have been distributed in the United States to patients considered to be at risk of returning to Mexico; the dissemination process for cards in Mexico was recently initiated. CDC conducted site visits in May 2003 to begin assessing the project.

Along with cost and project efficiency, the evaluation focuses on the effectiveness of the binational referral system in facilitating completion of therapy for TB patients traveling across the border and the feasibility of replicating the project in other sites. DTBE will

also collect anecdotal data by asking patients and providers to provide feedback on their personal feelings about answering questions on the binational TB cards. DTBE expects to compile solid data from the evaluation in the next year. Overall, DTBE conducts the project with a host of internal and external partners at federal, state and local levels. DTBE has developed an international referral form to assist TB patients from countries other than Mexico access care when they return to their countries of origin.

### ***Overseas TB Screening Process***

Mr. Subroto Banerji of DTBE conveyed that the goals of this activity are to reduce the importation of infectious TB into the United States and identify persons who require further TB evaluation upon U.S. entry. Public health research has demonstrated the relationship between migration of foreign-born persons and development or progression of TB disease. National TB surveillance data indicate that ~50% of reported TB cases among foreign-born persons are diagnosed within the first five years of initial U.S. entry. Of 60 million new arrivals to the United States each year, ~400,000 are identified as permanent residents and are required to complete the overseas medical evaluation process.

Of ~400,000 permanent residents, ~15,000 are identified with a TB condition. Analyses have shown that <1% of individuals with TB notification are sputum smear positive or infectious, while 5%-15% of these persons are diagnosed with active TB disease. The overseas TB screening process contains five components. First, the overseas medical examination is conducted by panel physicians and focuses on HIV, STDs, TB, substance abuse and other health conditions. Examinations that identify a public health condition are only valid for six months, while all others are in force for one year. Panel physicians are in-country medical providers appointed by the State Department. DGMQ provides technical instructions to panel physicians to conduct the overseas medical examination. The TB screening process includes a symptom review, chest x-ray and sputum smears.

Second, a TB classification is given to new arrivals after the overseas medical examination is completed. Class A is active infectious TB; persons must obtain a signed waiver from a U.S. health department and be non-infectious before getting a travel visa. Class B1 is clinically active non-infectious TB and Class B2 is clinically inactive TB. Only three Class A notifications were reported in the United States in 2001; the Philippines and Vietnam accounted for 30% of notifications. Third, the U.S. admissions process includes a review of the migrant's application by the State

Department prior to obtaining a travel visa. Public health conditions are noted on the application.

Fourth, domestic notification requires that results of the overseas medical examination and other immigration documentation be submitted to one of eight CDC quarantine stations located in airports in large metropolitan cities. CDC then generates notification to health departments. Fifth, follow-up with a TB program is conducted after the health department receives notification, the TB case is identified in the community and placed in care. Follow-up outcomes are documented and submitted to CDC. Although the overseas TB screening process focuses on a small proportion of persons migrating to the United States, the activity provides a critical opportunity to locate TB cases among identified high-risk populations. The process is critical to direct ongoing and future prevention and control efforts among new arrivals to the United States.

ACET made several observations about the overseas TB screening process. The law only applies to refugees and immigrants, but consideration should be given to extending the requirement to the ~60 million foreign students, persons on special work visas and other short-term arrivals to the United States. Most notably, ACET made a recommendation in 1990 calling for screening of foreign students, persons with work visas and other unscreened immigrants entering the United States. Agreement was reached to place the issue of national guidelines for B notification and other new arrivals who are not properly screened prior to U.S. entry on the next ACET agenda. ACET emphasized that programs will not be compelled to identify, screen and prioritize individuals at high-risk for LTBI treatment without the development of national guidelines.

CDC contracted the New Jersey Model Center to produce educational materials for civil surgeons with an expectation that visa adjusters in the United States would be required to be tuberculin skin tested. The New Jersey Model Center did not distribute the materials because CDC has not revised the guidelines to date. To address this issue, ACET made a motion for CDC to implement civil surgeons training materials developed by the New Jersey Model Center. **The motion was properly seconded by a voting member and unanimously passed.**

CDC pointed out that overseas TB screening is a step-wise process. Improvements in timely notification and other components of the existing system for immigrants and refugees must first be made before the law can be extended to other foreign populations and completion of LTBI therapy prior to U.S. entry. Actions CDC is taking in this effort include increasing the number of quarantine stations and providing training materials, specific criteria and continuing education for civil surgeons in the United States who perform health evaluations on individuals adjusting their immigration status. Moreover, CDC will initiate beta testing of an electronic notification system in August

2002. An electronic application that can be used by all quarantine stations is expected to be launched in the fall of 2003.

There being no further business or discussion, Dr. Kawamura recessed the ACET meeting at 4:28 p.m. on June 4, 2003.

### ***ACET Business***

Dr. Kawamura reconvened the ACET meeting at 8:40 a.m. on June 5, 2003 and entertained a motion to accept the previous meeting minutes. The motion was properly made and seconded by voting members. There being no further discussion, the February 4-5, 2003 ACET Meeting Minutes were unanimously approved. Dr. Kawamura led ACET in a review of future agenda items.

- Update on new diagnostic TB tools, vaccine and drug development, including global initiatives to facilitate these efforts.
- Presentation on national TB training programs; HIV or STD training models; training needs to meet the TB elimination goal; and the TB training and education strategic plan. Funding of TB educational curricula to be presented by a representative of the National Heart, Lung and Blood Institute.
- Status report on TB control in jails and other correctional settings.
- Status report on TB among immigrants, including the formation of national guidelines and an update of ACET's 1990 recommendations.
- Update on the CDC/ICE collaboration.
- Status report on TB elimination in the Southeast.
- Review of the document on essential TB components, including funding issues and continued support at state and local levels.
- Presentation on the Association of Public Health Laboratory Services Task Force document.
- Overview of TB information systems.
- Report on regionalization and program coordination between TB and other activities, particularly HIV/TB co-infection.
- Presentation on targeted testing and screening as TB elimination strategies, including the role of CDC cooperative agreements, private medical providers and health maintenance organizations (HMOs) in this issue.

In response to Dr. Kawamura's request, ACET proposed that representatives of the following agencies be considered as additional liaison members:

- American Academy of Family Practitioners
- American Academy of Pediatrics
- American College of Physicians
- American Medical Association
- American Public Health Association (APHA)
- American Public Health Informatics Organization
- Health departments at local, county and state levels: ASTHO and NACCHO
- TB technology companies: Global Alliance for TB Drug Development, STOP TB and STOP TB Partnership
- TB Training Education Network
- Vaccine Development Companies

### ***TB in the Southeastern United States***

Dr. Marisa Moore of DTBE conveyed that in 1993, CDC expanded its national TB surveillance system by including TB risk factors, drug susceptibility test results and treatment-related data. Also at this time, all states began submitting electronic case reports with TB-specific software provided by CDC. The TB case reporting system is now being revised again to be consistent with CDC's web-based National Electronic Disease Surveillance System. The Southeastern states include Alabama, Arkansas, Georgia, Louisiana, Mississippi, South Carolina and Tennessee (SE-7). Florida and Texas also had annual TB case rates above the national average, but were excluded from SE-7 due to the size, distinct epidemiology and population heterogeneity of the two states.

CDC surveillance data showed that annual TB case rates in SE-7 for both whites and blacks were consistently above the national average from 1991-2001, but a striking disparity was seen between the two groups. The TB rate among blacks was four times higher than the rate in whites in SE-7 and nine times than the rate in whites at the national level. Higher TB rates among blacks in SE-7 and the rest of the United States may reflect increased levels of ongoing transmission. Demographic factors of high TB case rates among both blacks and whites in SE-7 were associated with higher TB case rates in the region. Much of the historical disparity among racial groups has been attributed to socioeconomic status, particularly the effects of crowding. Most notably, 50% of the nation's population in severe poverty live in SE-7.

Overall, annual case rates in SE-7 and the rest of the country substantially declined by nearly 60% from 1991-2001. The decrease is consistent with indicators of successful programmatic performance in interrupting transmission and preventing the development of MDR-TB with DOT, timely treatment completion and low levels of anti-TB drug resistance. The declining trend was observed in both blacks and whites, but the higher initial rate and larger rate of decline among blacks outside of SE-7 may reflect the impact of TB outbreaks during the national resurgence of TB in the early 1990s. An increasing proportion of TB cases from foreign-born persons was also seen in SE-7, but the overall impact of 16% in SE-7 was much lower than 55% at the national level. Nearly 95% of TB cases occur in U.S.-born blacks or whites in SE-7.

CDC surveillance data found that rates of certain characteristics among TB patients in SE-7 were higher than those in the rest of the United States: excess alcohol use, drug use, incarceration and HIV co-infection. However, TB patients in SE-7 had lower rates of INH resistance, MDR-TB and four first-line drugs prescribed in the initial regimen than those outside the region. In 1999, 62% of SE-7 TB patients used DOT for all treatment compared to 47% of TB patients in the rest of the county. Rates of partial DOT use were similar, while rates of self-administered therapy were lower.

Data demonstrate that TB programs in SE-7 performed as well as or better than those outside the region. However, CDC has not yet analyzed the performance of contact investigations in SE-7. To address high TB case rates among blacks, CDC is collaborating with public health partners by funding demonstration projects in Chicago, Georgia and South Carolina. The goal of these initiatives is to identify innovative strategies to improve TB diagnosis, screening and treatment adherence in high-risk communities. Severe poverty in SE-7 potentially impacts TB morbidity in both blacks and whites and will also play a critical role in further defining TB epidemiology and developing effective public health interventions.

ACET acknowledged other problems in SE-7. TB control programs in SE-7 generally receive less funding per patient than those in other parts of the country. Some correctional facilities in Southeastern states refuse to cooperate and collaborate with TB control programs. For example, a local health department may have no knowledge if the jail screened inmates for HIV and TB upon initial booking. Some facilities also refuse to release TB test results to health departments after an inmate is released into the community. CDC should make strong efforts to revise its surveillance system to capture TB cases that pass through correctional settings.

Problems in SE-7 cannot be resolved without first addressing access to or utilization of health care among homeless persons and other individuals in poverty. Developing an HMO quality indicator for targeted screening, interventions and LTBI treatment for

persons in high-risk categories should be considered. CDC reported that a draft *MMWR* article on the SE-7 epidemiological data has been submitted to the editor. The document will be distributed to external reviewers from the Southeast TB Workgroup before being submitted for clearance. CDC hopes the article will raise awareness about TB disparities in SE-7 among the broader public health community. ACET suggested that CDC consider adding several topics to the upcoming *MMWR* article: genotyping data; a demographic breakdown of TB clusters in SE-7, *i.e.*, homeless persons; and South Carolina data describing demographics and psychosocial issues of TB problems in the state.

### ***Report on the Southeast TB Consultation***

Dr. Stephanie Bailey is a former ACET member and Chair of the Southeast TB Workgroup. She described outcomes from the consultation on TB disparities in the Southeast held on May 13-14, 2003. ACET members, CDC staff and outside experts participated in 11 conference calls from January-May 2003 to plan the consultation. The attendees included academicians, health care providers, public health leaders, policy- and decision-makers, as well as religious and community leaders from African American organizations and agencies that can impact TB control efforts in blacks.

The purposes of the consultation were to raise awareness of the disparity in TB rates among U.S.-born blacks compared to other U.S.-born persons; solicit support to eliminate TB in U.S.-born blacks; and develop recommendations to accelerate the decline in TB rates among U.S.-born blacks in SE-7. Presenters at the consultation emphasized several key points. The public health environment has changed over time due to evolving science, politics, communications and global involvement. Messages must be revised because “prevention” does not resonate with individuals as much as “protection.” TB control is both relational and local.

Media and available technology must be used to disseminate information, but all persons in the target population may not use cell phones or computers. The “Southeast” should be defined as the geographic area where disparities are greatest and historical influences of racism, discrimination and exploitation continue. Lack of education, teen parenthood, unemployment and no economic resources are significant demographic variables for TB disparities in SE-7, but poverty is the overriding factor. Inter-generational TB cases are prevalent in SE-7 families. Outreach strategies must reflect knowledge of the environment where TB patients live.

Communities and health departments must collectively provide holistic care that addresses more than TB. The gap between private providers and public health must be closed. TB can be eliminated in SE-7, but the fight must be sustained. TB disparities must be re-framed to create political will and leverage funding. The number of deaths from TB is not tolerated for other diseases with much lower mortality rates. Black churches play an influential and important role in black communities. Internal community issues that perpetuate and magnify communicable diseases must be addressed at the local level.

The consultation also included a panel discussion with a physician, TB caseworker and cured TB patient. Lessons learned from the dramatic decline of TB cases in Mississippi were outlined. Best practices and key elements from this state and other successful models in SE-7 should be disseminated. The consultation resulted in a number of recommendations. TB experts should be sent to communities and community-based organizations (CBOs) to discuss the problem and actions that can be taken. Other venues should be used for message delivery, including public service announcements, billboards, former TB patients, the National Minority Health Education Network, media outlets, direct person-to-person education and local gathering points, *i.e.*, churches, shelters, emergency rooms, liquor stores and national conferences.

Partnerships should be established with private-sector groups, CBOs and other organizations that serve the black community. Public school systems should be engaged and collaborations should be formed with historically black institutions of higher learning. Health departments should ensure that the racial/ethnic composition of staff is similar to the community. TB should be included in the Surgeon General's Health Disparities Report and the APHA conference. CDC should improve or establish relationships with a variety of organizations, including the National Medical Association, the Black Women's project, and executive directors of black fraternities and sororities.

Health departments should strengthen relationships with black communities to gain a better understanding of black culture; maintain respect for individuals; evaluate and improve community access to TB services; and create more community coalitions. Since the consultation, several actions were taken and commitments were made. A group of NGOs will draft a letter to the HHS Secretary underscoring the outrage with the TB disparity in SE-7. An abstract was submitted to conduct a TB workshop. A letter was drafted asking for the placement of TB on the conference agenda of the State Primary Care Associations in SE-7. A request will be made to establish a TB booth at the annual conference of the National Association of Community Health Centers (NACHC).

An article was written on the purpose and outcomes of the consultation and will be submitted to the National Association of Community Health Centers journal. HRSA will

support a study for NACHC to examine the process for community health centers to interface with local TB control programs. The Office of Minority Health is considering the possibility of allocating funds to SE-7. To advance this effort, a summary of the consultation will be provided to participants and ACET; a full report will be distributed to ACET as well. The Southeast TB Workgroup will continue to develop and refine specific strategies. A conference will be held in the future with community implementers and opinion leaders. "Your stand against TB is a stand against poverty, discrimination and inequity" was adopted as the consultation motto.

ACET members and CDC staff who attended the consultation agreed that the participants were extremely enthusiastic, passionate and committed to addressing the disparity in SE-7. Community leaders were particularly interested in obtaining epidemiologic data for their respective areas that could be used to advocate for TB prevention at the local level. The need to sustain the momentum and advance the consultation to concrete actions and clearly defined responsibilities was reinforced. Most notably, the gap must be bridged between organizational leaders who made commitments at the consultation and community members who will actually conduct activities.

To actively participate in this effort with the community, CDC will need to restructure its traditional culture that is driven by science. For example, community-based fears in facing the disease and its treatment will need to be identified and directly addressed with innovative strategies. The organization of health departments will need to be examined to minimize stigma in seeking care. Women and children are the primary patients of health departments, while men are perceived to only present for treatment of STDs. CDC's syphilis elimination campaign is a national model that can be reviewed for TB. In this approach, CDC developed a strategic plan for a disease and translated strategies into action at the community level. ACET applauded Dr. Bailey's solid leadership of the consultation and other workgroup activities.

CDC mentioned that the workgroup will need to maintain close communication, particularly since a group of NGOs is drafting a letter to the HHS Secretary. An ACET communication to the HHS Secretary before the NGO letter is sent would be the more appropriate strategy. Dr. Kawamura will draft a letter to the HHS Secretary summarizing the consultation and requesting that TB be considered for inclusion in the Surgeon General's Health Disparities Report. The letter will be distributed to ACET for review and comment before being sent. Other ACET members with an interest in joining the workgroup should inform Dr. Kawamura and Ms. Paulette Ford-Knights, the Committee Management Specialist. ACET recommended additional action steps that can be taken to advance the Southeast TB consultation.

- Convene a conference call within two weeks for the workgroup to review recommendations made at the consultation and clearly define roles and responsibilities, *i.e.*, specific items for ACET's ongoing involvement and follow-up versus DTBE's focus areas. The workgroup will distribute these findings electronically to ACET prior to the next meeting.
- Appoint Mr. Dave Crowder and Dr. Zachary Taylor as the DTBE points of contact with NGOs.
- Identify existing and upcoming opportunities to place TB on national agendas. For example, HHS may convene a health disparities conference in 2004 with a group of minority physicians. Many national organizations hold health fairs; TB materials that are appropriate for the lay public and targeted to at-risk populations could be distributed at these events.
- Develop a document that health departments can use as a guidance manual. Topics could include best practices from HIV, TB and chronic disease models.
- Take innovative approaches to actively involve the community and strengthen TB advocacy at the grassroots level. For example, provide local groups with a checklist that can be used to empower advocates to visit health departments and learn more about the TB control program, *i.e.*, needs, barriers and funding stream.
- Identify specific components of the syphilis elimination strategy that can be applied to TB, such as risk assessment and evaluation.
- Compile recommendations and action steps for ACET to publish an article on TB disparity in SE-7 in the future and develop a strategic plan for this issue.
- Invite a representative of the National Coalition for the Elimination of Tuberculosis to join the workgroup.
- Categorize recommendations made at the consultation into three groups to assist the workgroup in advancing to next steps: advocacy/visibility, partnerships and cultural sensitivity.
- Ensure that community-based efforts for TB disparity in SE-7 has a strong scientific component.
- Incorporate resource constraints in SE-7 into the action steps.
- Notify NGOs that participated in the consultation about the upcoming *MMWR* article on the SE-7 epidemiologic data.

### ***Closing Session***

The next ACET meeting is tentatively scheduled for October 1-2, 2003. The attendees applauded Dr. Kawamara for an outstanding effort in chairing her first ACET meeting.

There being no further business or discussion, Dr. Kawamura adjourned the ACET meeting at 11:34 a.m. on June 5, 2003.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

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Date

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L. Masae Kawamura, M.D., ACET Chair